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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/813,950	03/03/97	ASSMUS M	583-252-0-FW

IM11/1014

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EXAMINER	
SELLERS, R	

ART UNIT	PAPER NUMBER
1712	26

DATE MAILED: 10/14/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/813,950	Applicant(s) Assmus et al.
	Examiner Robert Sellers	Group Art Unit 1712

☒ Responsive to communication(s) filed on *Oct 8, 1998*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *3, 5, 7, 9, 11, 13, 15, and 17-24* is/are pending in the application.

Of the above, claim(s) *3, 5, 7, 9, 11, 13, and 15* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *17-24* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *24*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The finality of the rejection mailed July 27, 1998 is hereby withdrawn in response to the Information Disclosure Statement filed June 8, 1998.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-24 are rejected under 35 U.S.C. 102(b) as being anticipated by De Haan et al.

Example I in column 7, lines 8-22, the restraining phase, shows the melt extrusion of 83% by weight of Eudragit RSPM (an acrylic polymer within the ambit of claim 20 according to page 11, lines 3-8 of the specification) and 17% by weight of cetyl alcohol (a fatty alcohol embraced by the claimed flow improver as confirmed by page 14, line 6 of the specification). The chloroform blended with cetyl alcohol is evaporated prior to melting of the mass and extrusion. The mixture of Eudragit RSPM and cetyl alcohol is inherently non-homogeneous based on the types and amounts of acrylic polymer and flow improver within the claimed limits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller et al, Seth and European Patent No. 204,596.

Mueller et al discloses the melt extrusion (col. 3, lines 9-15) of at least 6% by weight (col. 2, lines 1-16) of an acrylic copolymer such as Eudragit RS (col. 4, Example 1) and as much as 30% by weight of pharmaceutical auxiliaries such as polyethylene glycols (col. 3, line 3 which is a suitable species of flow improver according to page 14, line 8 of the specification). It is a matter of ordinary skill in the art to employ a particular pharmaceutical auxiliary such as polyethylene glycols in order to impart a plasticizing effect which by definition improves the flow properties of the formulation.

Seth in column 6, Table 1, Examples 1 and 2 exhibits the melt mixing (col. 5, line 57 to col. 6, line 12) of 62% by weight of an Eudragit S 100 acrylic copolymer and 38% by weight of a polyethylene glycol 300-stearate (col. 6, line 39 which is an acceptable flow improver as indicated on page 14, line 21 of the specification). Although it is stated in column 4, lines 47-50 that a homogeneous solution is formed, no difference is seen between the prior art and claimed compositions based on the use of identical types and amounts of acrylic polymer and polyethylene glycol stearate.

The specification on page 6, lines 15-25 reveals that non-homogeneity is determined by the appearance of a film of the blend in a common solvent. There is no evidence distinguishing the claimed non-homogeneity throughout the claimed proportion ranges of acrylic plastic and flow improver over the closest prior art combination of Eudragit S 100 and polyethylene glycol 300-stearate wherein any data is presented objectively not by descriptors but by scientifically verifiable means such as differential thermoanalysis by DSC measurement (specification, page 7, lines 15-19).

The arguments pertaining to the European patent presented in the response filed October 8, 1998 (Paper No. 25) have been considered but are unpersuasive.

The specification on page 6, lines 15-18 states that "The mixture of the components A and B, in accordance with the invention, is regarded as non-homogeneous, if the components A and B are not compatible in the quantities used." However, page 7, lines 20-22 proposes that "Components A and B are essentially miscible in the melt, recognizable in the optical clarity of the melt." Page 11, lines 13-17 indicates "Flow improver B includes substances that can be mixed in an essentially homogeneous manner with the melt of polymer A . . . "

The disclosure describes the miscibility and homogeneity of the acrylic plastic and flow improver in the melt which encompasses the melt extrusion mixture of Eudragit RSPM and Precirol (i.e. glycerol palmito-stearate) of the European patent. Based on the description on page 6, line 23 to page 7, line 8 that "in the solidified melt, components A and B are present as separate phases," the composition of the European patent inherently exibibits the claimed non-homogeneity once the melt solidifies.

European Patent Nos. 40,590 and 502,642 are directed to Eudragit acrylic copolymers and cetyl alcohol or polyethylene glycol, respectively, which are mixed in an organic solvent as opposed to the claimed hot-melt mixing. Shukla et al sets forth a formulation of a wax such as glycerol fatty acid esters and additives including Eudragit acrylic polymers within an extensive list wherein no example with Eudragit is prepared.

Any inquiry concerning this communication should be directed to Robert Sellers at telephone number (703) 308-2399 (Fax no. (703) 305-5408).

ROBERT E. SELLERS
PRIMARY EXAMINER
GROUP 150

rs

10/14/98